

Kotchen & Low LLP

1745 KALORAMA RD. NW, STE. 101, WASHINGTON DC, 20009 | Tel: (202) 471-1995 | Fax: (202) 280-1128 | INFO@KOTCHEN.COM

June 17, 2019

Via ECF and Email

The Honorable Katherine Polk Failla
Thurgood Marshall United States Courthouse
40 Foley Square
New York, NY 10007

Re: Defendant's Request for Pre-Motion Conference in *3B Medical, Inc. v. SoClean, Inc.*, No. 1:19-cv-03545-KPF

Dear Judge Failla:

Plaintiff 3B Medical, Inc. respectfully submits that Defendant SoClean, Inc.'s proposed motion to dismiss is futile. The Lanham Act, 15 U.S.C. § 1125(a)(1), "creates a cause of action for unfair competition through misleading advertising or labeling." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 107 (2014). To violate the Act, "[a] challenged message [must be] (1) either literally or impliedly false, (2) material, (3) placed in interstate commerce, and (4) the cause of actual or likely injury to the plaintiff." *Church & Dwight Co. v. SPD Swiss Precision Diagnostics GMBH*, 843 F.3d 48, 65 (2d Cir. 2016).

3B Satisfies the Injury Standard. The injury standard for Lanham Act liability "is whether it is likely that [defendant]'s advertising has caused or will cause a loss of [plaintiff's] sales," which can be established when defendant and plaintiff "are competitors in a relevant market" and plaintiff demonstrates a "logical causal connection between the alleged false advertising and its own sales position." *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980).

3B's allegations meet this standard. 3B and SoClean both make and sell medical devices that sanitize continuous positive airway pressure ("CPAP") equipment.¹ Compl. ¶¶ 11-25. SoClean is the largest market competitor, with roughly a ninety percent market share. *Id.* ¶ 142. SoClean's devices work by producing and emitting ozone gas, which regulators and medical professionals widely consider unsafe for humans to breathe. *Id.* ¶¶ 28-92. But SoClean maintains its market share by doggedly misrepresenting these basic facts to consumers. *Id.* ¶¶ 96-140. The Complaint identifies several of these false claims: that SoClean's devices rely on "activated oxygen" rather than ozone gas; are "safe" and "healthy"; use no "chemicals" or "harsh chemicals"; use the same sanitizing process as hospitals; have filter cartridges that convert "activated oxygen" into "regular oxygen"; and are sealed or a "closed loop" so that no "activated oxygen" escapes. *Id.* In contrast to SoClean, 3B's device (the Lumin) uses a UV-C light, rather than ozone, to sanitize CPAP equipment. *Id.* ¶¶ 23-24. SoClean's misrepresentations all concern the core attribute distinguishing the two products. This leads consumers to purchase SoClean's device when they would otherwise purchase the Lumin, enabling SoClean to maintain its dominant market position. *Id.* ¶ 142-43.

This diversion of sales is "the paradigmatic direct injury from false advertising." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 138 (2014). And courts have consistently held that it suffices to show the injury element of a § 1125(a) claim. *E.g., Danone, US, LLC v. Chobani, LLC*, 362 F. Supp. 3d 109, 118 (S.D.N.Y. 2019) ("Nor can it plausibly be

¹ CPAP machines are used to treat sleep apnea and respiratory illnesses. Compl. ¶¶ 15-17.

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argued that Dannon, as a direct competitor to Chobani, has not established the sort of competitive injury that suffices for Lanham Act purposes”); *In re Elysium Health-Chromadex Litig.*, 2018 U.S. Dist. LEXIS 168417, at *36 (S.D.N.Y. Sep. 27, 2018) (“A claim by a direct competitor, as CMDX is to Elysium, constitutes ‘the paradigmatic direct injury from false advertising.’ CMDX alleges . . . that it suffered direct competitive injury.”) (quoting *Lexmark*, 572 U.S. at 138).

SoClean’s cherry-picked quotes from factually dissimilar caselaw—designed to make the pleading standard seem insurmountable—do not alter this conclusion. Contrary to SoClean’s representations, the Second Circuit has “reject[ed] [the] assertion that a presumption of injury is only applicable to cases of comparative advertising mentioning the plaintiff’s product by name.” *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 259 (2d Cir. 2014). Rather, “[w]hile ‘our circuit has expressly disfavored presumptions of harm in cases where the *products are not obviously in competition* . . .’ the products and parties here are obviously in direct competition.” *Id.* at 60 (emphasis in original) (citations omitted). Moreover, SoClean’s cases concern whether a plaintiff proved his claims at trial. See *Ortho Pharm. Corp. v. Cosprophar, Inc.*, 32 F.3d 690 (2d Cir. 1994), *abrogated by Lexmark*, 572 U.S. 118; *Gnosis*, 760 F.3d at 247. But even at trial, the burden is not as onerous as SoClean suggests. Proving injury for liability (as opposed to damages) turns on “whether it is likely that [defendant’s] advertising has caused or will cause a loss of [plaintiff’s] sales, not whether [plaintiff] has come forward with specific evidence that [defendant’s] ads actually resulted in some definite loss of sales.” *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d Cir. 1980); see also *Church & Dwight*, 843 F.3d at 72 (“At the liability stage, the Lanham Act demands only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising.”) (citation and internal quotation marks omitted).

SoClean’s Other Reasons for Dismissal. SoClean’s other reasons for dismissal are equally groundless. First, a New York common-law claim for unfair competition is “a broad and flexible doctrine” encompassing “any form of commercial immorality” beyond just “palming off.” *Metropolitan Opera Ass’n v. Wagner-Nichols Recorder Corp.*, 101 N.Y.S.2d 483, 488-92 (N.Y. Sup. Ct. 1950) (collecting cases and reviewing the history of New York common-law unfair-competition jurisprudence), *aff’d* 107 N.Y.S.2d 795 (N.Y. App. Div. 1951).

Second, 3B’s cause of action is consistent with the FDA’s regulations under the Food Drug and Cosmetics Act, but this is a suit for violations of the Lanham Act, and the former does not preclude the latter. *POM Wonderful*, 573 U.S. at 113-21 (holding that FDA regulation does not preclude Lanham Act suits); *Church & Dwight*, No. 14-585-AJN, 2015 U.S. Dist. LEXIS 113309, at *9 (S.D.N.Y. Aug. 26, 2015) (same in the medical device context), *aff’d* 843 F.3d at 62-65. As the Supreme Court has explained, “[b]y ‘serv[ing] a distinct compensatory function that may motivate injured persons to come forward,’ Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, ‘provide incentives’ for manufacturers to behave well.” *POM Wonderful*, 573 U.S. at 115.

Third, materiality requires that the “falsity had the capacity to adversely affect the plaintiff’s business by influencing consumer purchasing decisions.” *Church & Dwight*, 843 F.3d at 70-71 & n.11. Although a misrepresentation about an inherent quality is always material, it is not the only type of representation that can be material. Restatement (Third) of Unfair Competition § 3, cmt. c. (representation that “in some other manner relates to the desirability of the proposed transaction may also be material”). Regardless, the claim that the SoClean works in the same manner as hospital sanitizing *is* inherent because it goes to the very nature of the device and, more

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importantly, read in context, implies that the device is safe, and safety is always material. *In re NJOY*, No. 14-00428, 2014 U.S. Dist. LEXIS 196586, at *29 (C.D. Cal. May 27, 2014) (collecting cases and explaining that “representations concerning the health and safety effects of products are important to consumers, and hence that claims based on such representations . . . should survive dismissal”); FTC Deception Policy Statement, 103 F.T.C. 110, 174, 176-83 (1984) (explaining that health and safety claims are material to consumers).

Fourth, SoClean’s advertising is materially false—not puffery. A party cannot coin whimsical phrases (like activated oxygen) to avoid the established meanings of words. *Johnson & Johnson v. GAC Int’l*, 862 F.2d 975, 982 (2d Cir. 1988) (holding that use of the coined term “polysapphire” to refer to non-sapphire was “false on its face”); *Church & Dwight*, 2015 U.S. Dist. LEXIS 86170, at *58-59 (S.D.N.Y. July 1, 2015) (finding that “efforts to avoid acknowledging the existence and import of a standard convention . . . do not suffice to render [] advertising truthful”). And the other challenged messages are factual and capable of misleading consumers when read in context of SoClean’s other affirmative statements and omissions. *See e.g., Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1125-26 (N.D. Cal. 2010) (“The insistence that a product with (allegedly) dangerous additives is nonetheless ‘wholesome,’ . . . , arguably could mislead a reasonable consumer. Accordingly, at this juncture, the term ‘wholesome’ cannot be deemed to constitute non-actionable puffery.”); *Healthier Choice Flooring v. CCA Glob. Partners*, No. 1:11-2504, 2013 U.S. Dist. LEXIS 193200, at *18-19 (N.D. Ga. Mar. 5, 2013) (holding that claims product was “healthier” were actionable, rather than puffery, when read in context). Moreover, the existence of a disclaimer (and plaintiffs do not believe that SoClean’s ozone disclosures even qualify as such) does not render a false statement non-actionable. *Mantikas et al. v. Kellogg Co.*, 910 F.3d 633 (2d Cir. 2018) (holding that “reasonable consumers should [not] be expected to look beyond misleading representations on the front of the box to discover the truth”); *Church & Dwight*, 2015 U.S. Dist. LEXIS 86170, at *58 (a “disclaimer that ‘purports to change the apparent meaning of the claims and render them literally truthful, but which is so inconspicuously located . . . that readers tend to overlook it, will not remedy the misleading nature of the claims’”) (citation omitted). Finally, SoClean’s argument that it does not use “harsh chemicals” contradicts the Complaint, which is not only improper for a Rule 12(b)(6) motion but is contrary to SoClean’s own admissions, so the contention lacks any basis in fact. *See Ex. A*, SoClean Press Release of Jan. 24, 2013 (explaining that ozone is a powerful yet dangerous sanitizer, akin to chlorine bleach).

Because this case presents a quintessential Lanham Act false advertising claim, SoClean’s proposed Motion to Dismiss is futile.

Sincerely,

Daniel Kotchen

CC: All Counsel (via ECF)